

Atty. Docket No.: 02600/50001

5                   **METHOD AND APPARATUS FOR COVERING A STENT****FIELD OF THE INVENTION**

10           The present invention relates generally to stents  
for implanting into a living body. In particular, the present  
invention relates to a biological covering for a stent  
suitable for implanting into a variety of lumens.

**BACKGROUND OF THE INVENTION**

15           In an attempt to prevent restenosis, metallic  
vascular stents have been permanently implanted in coronary or  
peripheral vasculature. These stents are typically delivered  
intraluminally by a catheter and expanded in place to support  
20   a diseased portion of an artery.

One shortcoming of these conventional stents is that even after stent implantation, restenosis can still occur. Another shortcoming is that during the implantation of the stent, the stent may cause particles to discharge from the artery wall through the open cell. These dislodged particles can embolize in the bloodstream, and may cause catastrophic effects.

In an attempt to reduce these problems, coverings have been proposed for stents. These coverings have been made from artificial materials, such as PTFE. As of yet, however, coverings made from artificial materials have not proven successful. This may be because of the poor biocompatibility of such materials.

There is also some experience using biological tissue such as bovine pericardium to build a covering for a stent that is more biocompatible than coverings made from artificial materials. Preliminary results with bovine pericardium have been encouraging from the point of view of biocompatibility.

The current method, however, of creating a covering using biological tissue is simplistic. A rectangular piece of pericardium is harvested from a bovine source. The pericardium is then, after being prepared so that it is suitable for implantation, rolled into a cylinder. The

abutting edges of the pericardium are sewn together to create a covering. This covering is then placed over a stent.

There is an inherent disadvantage in this cut and  
5 sew approach to creating a covering. Biological tissue has a  
very small expansion range. Therefore, the diameter of the  
cut and sewn cylinder of tissue is limited to a very small  
range. This limits the stent to a very small range of  
expansion diameters, limiting the utility of the stent. This  
10 also limits the difference in diameter between the stent as  
delivered and the stent at its expanded state, increasing  
significantly the profile of the delivery system required for  
a given supported diameter.

## 15 SUMMARY OF THE INVENTION

In one embodiment of the present invention, biological fibers or biodegradable fibers or fiber groups are  
arranged as interwoven threads to make an expandable tube.

20 The interwoven threads are arranged with an acute angle  
between the interwoven threads while the stent is unexpanded.  
When the stent is expanded, the angle between the interwoven  
threads increases. This allows the stent covering to be  
expanded to a variety of diameters.

25 In another embodiment, a strip of pericardium is  
helically wound around a stent with a substantial overlap  
between adjacent windings while the stent is in a first,

unexpanded diameter. During expansion to a second expanded diameter, the strips will slide over the stent and unwrap for a smaller number of loops, but will still completely cover the stents. In a further enhancement to this embodiment, the edges of the spiral wrapping are formed into locking folds to prevent the spiral loops from separating during expansion of the stent and covering.

Accordingly, it is an object of the current invention to provide an improved biological tissue covering for a stent, and a method for producing the same.

Further objectives and advantages of the subject invention will be apparent to those skilled in the art from the detailed description of the disclosed invention.

#### **BRIEF DESCRIPTION OF THE DRAWINGS**

Fig. 1 shows an interwoven stent covering in an unexpanded state.

Fig. 2 shows an interwoven stent covering in an expanded state.

Fig. 3 shows a strip of pericardium used to form a stent covering.

Fig. 4 shows a spiral wrapped stent covering in an unexpanded state.

Fig. 5 shows a spiral wrapped stent covering in an expanded state.

Fig. 6 shows a partial cross-sectional view of one embodiment of a spiral wrapped stent covering in an unexpanded state.

Fig. 7 shows a partial cross-sectional view of one embodiment of a spiral wrapped stent covering in an expanded state.

#### DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

The subject invention will now be described in detail for specific preferred embodiments of the invention, it being understood that these embodiments are intended only as illustrative examples and the invention is not to be limited thereto.

Figs. 1 and 2 show an endoprosthesis according to this invention. A luminal endoprosthesis 20 has a tubular stent 22 expandable from a first diameter  $D$  shown in Fig. 1 to a second diameter  $D'$  shown in Fig. 2. Stent 1 may be a self-expanding stent or a balloon expandable stent. One example of a suitable balloon expandable stent is illustrated in U.S. Patent No. 5,807,404, the disclosure of which is hereby incorporated by reference.

The stent has a covering 24 formed of biological fibers. The biological fibers may be obtained by dissolving any suitable biological tissue, such as bovine, ovine, or porcine pericardium tissue. Alternatively, the fibers can be  
5 formed from other material, such as Cut-Gut collagen threads.

As shown in Fig. 1, the individual fibers 26 are interwoven, and form an angle 28 with respect to the longitudinal axis 30 of the stent 22. When the stent is at  
10 the unexpanded diameter D, the angle 28 is approximately 30°.

Typically, the endoprotheses will be implanted... using a conventional balloon angioplasty procedure. In this procedure, the stent 22 and associated covering 24 are placed  
15 onto the balloon at the end of a balloon catheter and delivered to the site of the restricted or diseased portion of an artery. The stent and covering are then expanded into contact with the lumen by inflating the balloon. The catheter can then be deflated and withdrawn, leaving the stent and  
20 covering at the treatment site. As shown in Fig. 2, upon expansion from the first diameter D to the second diameter D', the fibers of the expandable coating change orientation so that they are at a greater angle 28 with respect to the longitudinal axis 30 of the stent 20 then when they are in the  
25 first diameter D. The angle 28 at the expanded diameter D' is dependent upon the amount of expansion of the stent. Therefore, depending on the size of the lumen which the stent is inserted into, the angle 28 varies from 30° to 90°.

Another embodiment of the biological stent covering is shown in FIGS. 3-5. In this embodiment, pericardium tissue is collected and prepared in a manner known to those skilled in the art. The pericardium tissue is then cut into a single strip 50 with lateral edges 52. A supporting stent 54 with an unexpanded diameter of  $D$  and an expanded diameter of  $D'$  is provided. The strip 50 is helically wound around a supporting stent 54 while the stent is in a collapsed state with a diameter of  $D$  to form a series of helical windings 56. The lateral edges 52 of adjacent helically windings 56 are arranged so that the lateral edge 52 of one winding overlaps the adjacent winding.

Upon expansion of the stent from the diameter  $D$  to  $D'$ , the helically wound strip of pericardium unwinds. However, because of the overlap between adjacent strips, no area of the stent is uncovered during and after expansion of the stent and covering. The ratio between the maximal expanded diameter without causing gaps, and that of the unexpanded stent equals the overlap ratio of the stent.

An alternative embodiment of the spiral wrapped stent is shown in FIGS. 6 and 7. In this embodiment, the edges 52 of the pericardium strip 50 are provided with interlocking edges 60, 62. The right interlocking edge 62 is formed by folding the edge of the pericardium strip over itself. The left interlocking edge 64 is formed by folding

the edge of the pericardium strip over itself; the left edge is folded in the opposite direction as the right edge.

The strip with the interlocking edges is helically wound around the stent in the same manner as described above with respect to the embodiment illustrated in FIGS. 4 and 5. Special care is taken to make sure that the right interlocking edge 62 is placed between the right edge 66 and the left interlocking edge 64 of the adjacent spiral wrap. Upon expansion of the stent, the right and left interlocking edges mate together. In this manner, the interlocking edges assure that there is no gaps in the coverage of the expanded stent, as illustrated in Fig. 7.

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